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Calcium requirements of pregnant women in The Gambia

Submission date	Recruitment status	[_] Prospectively registered
11/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2024	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Calcium requirements of pregnant women in The Gambia

Study objectives
Calcium intakes of pregnant women in rural areas of The Gambia are considerably below recommended levels. There is evidence to suggest that low calcium intakes during pregnancy

may be associated with an increased incidence of pregnancy-induced hypertension, reduced maternal bone mineral content, low breast-milk calcium concentrations post-partum, and sub-optimal bone development and growth of the child. The aim of this study is to determine whether pregnant Gambian women would benefit from an increase in calcium intake.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Research Council (MRC)/Gambian Government Joint Ethics Committee (ref: SCC/EC 585/559).

Primary study design
Interventional

Study design
Randomised double blind placebo controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Calcium deficiency in pregnancy

Interventions
1500 mg Calcium (Ca) orally per day or placebo until delivery.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Calcium

Primary outcome(s)
1. Maternal blood pressure at 36 - 38 weeks gestation
2. Breast-milk calcium concentration during laction
3. Post-partum bone mineral content of mother and baby

Key secondary outcome(s)
1. Infant growth and development:
1.1. Weight, measured within 24 hours of birth and at 2, 13 and 52 weeks
1.2. Crown-heel length, measured within 5 days from birth and at 2, 13 and 52 weeks
1.3. Head circumference measured within 5 days from birth and at 2, 13 and 52 weeks
2. Infant blood pressure and growth, measured every two years from age 3
3. Maternal post-partum blood pressure, measured at 2, 13 and 52 weeks post-partum

Completion date
31/12/2000

Eligibility

Key inclusion criteria
Consenting pregnant women at booking.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
No specific exclusion criteria at booking.

Date of first enrolment
01/01/1995

Date of final enrolment
31/12/2000

Locations

Countries of recruitment
United Kingdom

England

Gambia

Study participating centre
MRC Human Nutrition Research
Cambridge
United Kingdom
CB1 9NL

Sponsor information

Organisation

Medical Research Council (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2006		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	01/12/2011		Yes	No
Results article	follow-up study results	01/09/2013		Yes	No
Results article	results	01/10/2013		Yes	No

Results article	follow-up on blood pressure and growth	18/04/2024	11/06/2024	Yes		No